IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TYLER DIVISION

RETRACTABLE TECHNOLOGIES, INC.,	§	
	§	Civil Action No. 6:08-cv-00120-LED
Plaintiff,	§	
	§	(JURY TRIAL)
v.	§	
	§	
OCCUPATIONAL & MEDICAL INNOVATIONS, LTD.,	§	
	§	
	§	
Defendant.	§	

MOTION OF DEFENDANT OCCUPATIONAL & MEDICAL INNOVATIONS, LTD.
FOR JUDGMENT AS A MATTER OF LAW

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I. INTRODUCTION

Defendant Occupational & Medical Innovations, Ltd. ("OMI") moves for judgment as a matter of law on the following issues:

(1) judgment of noninfringement, because plaintiff Retractable Technologies, Inc. ("RTI") failed to present evidence from which a reasonable jury, applying the correct construction of the claims, could conclude that OMI's syringes satisfy two requirements of the claims: (i) that some clamping or frictional force keeps the needle in the projecting position and (ii) that the tip of the plunger contacts the outer part of the needle holder (which RTI points to as the retainer);

(2) judgment of noninfringement for the unasserted claims of the '584 patent, i.e., claims 3-6, 8-17, 20-23, and 25-28;

(3) judgment of invalidity for lack of enablement, because OMI presented clear and convincing evidence that the '584 patent does not teach a person of ordinary skill in the art how to make and use the full scope of the claimed invention without undue experimentation, specifically, (i) how to make and use a retainer and needle holder made from a single piece of material and (ii) how to make and use a retainer in view of the patent's disclosure of Santoprene® 181-55 for the retainer, and RTI failed to present evidence to the contrary from which a reasonable jury could conclude that the full scope of the claims was enabled;

(4) judgment of invalidity for failure to disclose the inventors' best mode for practicing the claimed invention, because OMI presented clear and convincing evidence that the '584 patent does not disclose (i) the inventors' best mode material, Santoprene® 283-40, for the retainer and plunger plug or (ii) the inventors' preference for a needle holder with a needle seat, and RTI failed to present evidence to the contrary from which a reasonable jury could conclude that the best mode was disclosed;

(5) judgment that RTI's trade secret misappropriation claim is barred as a matter of law, because OMI presented evidence that RTI failed to bring its claim within the three-year Texas statute of limitations, and RTI failed to present evidence to the contrary from which a reasonable jury could conclude that RTI's claim is not barred; and

(6) judgment that OMI did not misappropriate any RTI trade secrets, because RTI failed to present evidence from which a reasonable jury could conclude that OMI misappropriated any RTI alleged trade secrets that resulted in any damage to RTI.

II. LEGAL STANDARDS

Federal Rule of Civil Procedure 50(a)(1) provides:

> If a party has been fully heard on an issue during a jury trial and the court finds that a reasonable jury would not have a legally sufficient evidentiary basis to find for the party on that issue, the court may: (A) resolve the issue against the party; and (B) grant a motion for judgment as a matter of law against the party on a claim or defense that, under the controlling law, can be maintained or defeated only with a favorable finding on that issue.

"Under Rule 50, a court should render judgment as a matter of 'law when a party has been fully heard on an issue and there is no legally sufficient evidentiary basis for a reasonable jury to find for that party on that issue.'" *Reeves v. Sanderson Plumbing Prods.*, 530 U.S. 133, 149 (U.S. 2000) (citing Fed. R. Civ. P. 50(a)); *Palasota v. Haggar Clothing, Co.*, 499 F.3d 474, 480 (5th Cir. 2007). Because motions under Fed. R. Civ. P. 50 are procedural matters not unique to patent law, regional circuit law controls. *Summit Tech., Inc. v. Nidek Co.*, 363 F.3d 1219, 1223 (Fed. Cir. 2004).

When a motion for judgment as a matter of law is renewed after a jury verdict, the record is reviewed for the presence of substantial evidence supporting the jury's express or implied finding, and for legal error. *See Motorola, Inc. v. Interdigital Technology Corp.*, 121 F.3d 1461 (Fed. Cir. 1997) (applying the rule and affirming jury verdict except as to the

invalidity of certain claims). When a trial court determines in a post-verdict motion what the law correctly is, the court then determines whether any juror could reasonably have reached—on the evidence presented at trial—the verdict challenged by the post-verdict motion. If the answer is no, the trial court reverses the jury verdict for failure of proof on the correct legal standard, and denies the loser a second trial on the correct law. *See Exxon Chemical Patents, Inc. v. Lubrizol Corp.*, 64 F.3d 1553, 1560 (Fed. Cir. 1995). "[N]otwithstanding the jury's verdict, on review of a motion for JMOL the court retains the power and duty to say what the correct law is and then to examine the factual issues submitted to the jury and determine whether findings thereon are supported by substantial evidence and support the verdict under the law." *Markman v. Westview Instr., Inc.*, 52 F.3d 967, 975 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370, 116 S. Ct. 1384 (1996).

The substantial evidence standard requires more than a mere scintilla of evidence. *Biodex Corp. v. Loredan Biomedical, Inc.*, 946 F.2d 850 (Fed. Cir. 1991). It requires relevant evidence which, considered as a whole, would allow a reasonable jury to find the facts needed to support the verdict in light of the applicable law. *Baxter Health Care Corp. v. Spectrmed, Inc.*, 49 F.3d 1575, 1582 (Fed. Cir. 1995). If a court erroneously submits an issue to the jury on which there is neither evidence nor argument, it is obligated to grant a motion for judgment as a matter of law on that issue. *Lear Siegler, Inc. v. Sealy Mattress Co. of Michigan, Inc.*, 873 F.2d 1422, 1426 (Fed. Cir. 1989).

III. JUDGMENT OF NONINFRINGEMENT SHOULD BE GRANTED AS A MATTER OF LAW

Judgment as a matter of law of no infringement is appropriate if no reasonable fact finder could determine that the accused devices meet every limitation of the properly construed claims. *Elkay Mfg. Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 980 (Fed. Cir. 1999). To establish infringement, RTI was required to prove by a preponderance of the evidence that the accused OMI syringes

included every limitation of at least one asserted claim. *General Mills, Inc. v. Hunt-Wesson, Inc.*, 103 F.3d 978, 981 (Fed. Cir. 1997).

A. RTI Failed To Present Evidence From Which A Reasonable Jury Could Conclude That OMI's Syringes Include The Friction Or Clamping Force Requirement Of The "Retainer" Limitations

The Court interpreted "retainer member" in claim 1 of the '584 patent and "transverse retainer" in claims 18-19 and 24 of the '584 patent to mean "a non-retractable part of the retraction mechanism that uses some clamping or frictional force to keep the needle in the projecting position until released." When the Court's interpretation of the retainer limitations is properly applied, OMI's syringes do not infringe as a matter of law.

OMI and RTI's respective experts both testified about what the Court's claim construction means. RTI's expert, Mr. Sheehan, testified that the Court's claim construction does not require the clamping or frictional force to be sufficient on its own to hold the needle in a projecting position. [Sheehan, 12/15/09 PM Tr. 149:22-150:1] He stated that the friction "holds the needle or helps hold the needle, certainly, or it can entirely hold the needle in the projecting position…." [Sheehan, 12/15/09 PM Tr. 150:23-151:1] In short, it is RTI's position that the claim encompasses a structure using a flange plus friction to hold the needle in the projecting position, no matter how small the friction force is. Mr. Sheehan effectively told the jury the "some clamping or frictional force" in the Court's claim construction could be any amount at all.

By contrast, OMI's expert, Mr. Leinsing, testified that some clamping or frictional force to keep the needle in the projecting position "means that you're using a portion of the total frictional force that's there to hold the needle in the projecting position," i.e., the clamping or frictional force must exceed the spring force. [Leinsing, 12/17/09 PM Tr. 12:2-7; 77:8-78:8] This is consistent with this Court's statement in the claim construction opinion that "A clamping or frictional force between the needle retraction mechanism and the inner wall of the syringe

barrel holds the needle holder in position during the administration of an injection. The frictional force opposes and exceeds the force of the spring." [Claim Construction Memorandum Opinion (Dkt. 113) at 1-2] Both experts agreed that the Court's claim construction does not say that the friction force "helps to keep" the needle in the projecting position. [Leinsing, 12/17/09 PM Tr. 11:22-12:1; Sheehan, 12/16/09 AM Tr. 30:18-31:3]

RTI and Mr. Sheehan's claim construction position is wrong as a matter of law, because it renders the Court's claim construction indefinite. If "some clamping or frictional force to keep the needle in the projecting position" includes any amount of clamping or frictional force in combination with some other holding mechanism (such as a flange or lip), then the claim is indefinite, because it is impossible to determine whether a device infringes. Such an interpretation does not permit the public to determine whether or not they are infringing the claims, because the amount of frictional force is completely undefined. *See Honeywell Int'l, Inc. v. ITC*, 341 F.3d 1332, 1338 (Fed. Cir. 2003). Mr. Sheehan's claim construction position is also incorrect because it effectively eliminates the phrase "to keep the needle in the projected position" from the claim construction. In other words, Mr. Sheehan did not address the fact that the friction must serve the purpose of keeping the needle in the projected position and Mr. Sheehan's position makes this purpose superfluous.

RTI and Mr. Sheehan's interpretation of the Court's claim construction is also wrong as a matter of law because it improperly encompasses the flange/fluid seal structure used in the prior art Tsao '018 patent that was distinguished from the invention in the specification of the '584 patent. Specifically, the '584 patent states that "[t]he rare prior art that employs a front mounted retraction mechanism in a one-piece barrel with a plugged hollow plunger, Tsao U.S. Pat. No. 5,084,018, among other things … employs engaging flanges to secure all retraction parts…."

[PTX 4, '584 patent, col. 1:66-col. 2:7] Both experts testified that Figure 6 of the Tsao '018 patent shows a flange 26 on the barrel that keeps the retraction parts from moving downward in the barrel and friction between the ring member 20 and the barrel. [Sheehan, 12/16/09 AM Tr. 35:7-36:8; Leinsing, 12/17/09 PM Tr. 13:5-14:16]

The '584 patent then goes on to distinguish the prior art: "The prior art has not recognized a retraction mechanism with separable parts that relies entirely on ***clamping force or friction at a smooth walled reduced diameter transition zone in the barrel***…." [PTX 4, '584 patent, col. 2:14-17, emphasis added] Finally, the Summary of the Invention characterizes the invention as using clamping or frictional force to hold the needle in place:

> The outwardly facing surface on the circular head of the needle holder is slightly greater in diameter than the circular inward facing surface in the wall at the most constricted portion where the nose begins. The needle holder is thus clamped in position by hoop stresses induced in the outer body and held in position by frictional holding force.

[*Id.*, col. 3:33-38; Leinsing, 12/17/09 PM Tr. 15:2-12].

Thus, in the Background of the Art and Summary of the Invention sections, the '584 patent describes a feature of the invention (holding the needle holder in place by clamping or frictional force) and criticizes the prior art Tsao patent for its use of flanges to hold the retraction mechanism in place, even though there was also a frictional fit between the barrel and ring member 20 in the Tsao patent. Where "the general summary or description of the invention describes a feature of the invention … and criticizes other products … that lack the same feature, this operates as a clear disavowal of these other products…." *Astrazeneca, AB v. Mutual Pharm. Co., Inc.*, 384 F.3d 1333, 1340 (Fed. Cir. 2004); *see also Sci-Med Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1341 (Fed. Cir. 2001) ("where the specification makes clear that the invention does not include a particular feature, that feature is deemed to be outside

the reach of the claims….") RTI and Mr. Sheehan's argument that "some" clamping or frictional force includes an amount of frictional force less than the spring force is contrary to this clear disavowal.

Mr. Sheehan even agreed to the similarities between the flange/friction fit in the Tsao '018 patent and the structure in OMI's syringes. He admitted that because the barrel in Tsao is a one-piece barrel, "to form this barrel, you would have to use a core pin that's inserted from the back of the barrel in the mold," that the core pin, upon completion of the molding process has to be withdrawn, and that the flange 26 has to be relatively small in order to withdraw the core pin. [Sheehan, 12/16/09 AM Tr. 36:12-37:6] He then admitted that the OMI syringes have a lip, that a core pin is used to form the barrel, that you have to withdraw the core pin, and that you have to get the core pin to pass the lip. Then he agreed that the same thing would have to happen in the Tsao patent—the flange in Tsao would have to be relatively small to withdraw the core pin. [*Id.* 37:7-25] Because of the clear disavowal of the Tsao structure, OMI's use of a lip for retention and friction for a fluid seal does not satisfy the requirement of "some clamping or frictional force to keep the needle in the projecting position until released."

Mr. Sheehan's rebuttal to this clear disavowal in the '584 patent was that the passages noted above are "entirely irrelevant to the claims in suit. It has nothing to do with them. The claims in suit are about tilting." [Sheehan, 12/15/09 PM Tr. 154:9-20] That argument is misplaced, because the claims include a retainer limitation, which the Court has construed as requiring some clamping or frictional force to keep the needle in the projecting position. Mr. Sheehan also tried to explain away this clear disavowal by arguing that the statement "[t]he prior art has not recognized a retraction mechanism with separable parts that relies entirely on ***clamping force or friction at a smooth walled reduced diameter transition zone in the***

barrel…" [PTX 4, '584 patent, col. 2:14-17, emphasis added] refers only to Figure 1, because Figure 8 uses friction between the retainer and barrel but a bridge between the retainer and needle holder. [Sheehan, 12/15/09 PM Tr. 155:10-156:4] But that is an obvious misinterpretation of the passage, which is clearly talking about friction at the barrel surface, not between the retainer and needle holder.

Mr. Sheehan's argument about Figures 1 and 8 is also inconsistent with the claim construction order in the *Becton Dickinson* case (Civil No. 2:07-CV-250), which was the basis for the parties' agreement on the construction of the retainer limitations in this case. The court in *Becton Dickinson* noted that there were two embodiments of the retainer and needle holder described in the specification. The first embodiment is one in which "a pair of frictional holding forces function to retain the needle holder in the projecting position: a frictional force between the wall of the syringe and the retainer member, and another between the retainer member and the needle holder." [Civil No. 2:07-CV-250, January 20, 2009 Claim Construction Order (Dkt. 122), p. 16] This is the embodiment depicted in Figure 1. The second embodiment is one in which "the needle holder and retainer are welded or tack molded [sic] together." [*Id.*] As to this second embodiment, the Court stated that "although this weld or tack mold [sic] holds the needle holder and retainer member together, there is still a clamping or frictional force between the wall of the syringe and the retainer member." [*Id*.] The Court then stated that "[w]ithout this force between the wall of the syringe and the retainer member, the syringe would be inoperable—it would be unable to retain the needle in a projecting position. Thus, the retainer member can only function through the use of a frictional or clamping force." [*Id.*]

Mr. Sheehan agreed that the embodiments in Figures 1 and 8 of the patent, "the only holding force between the barrel and the retainer is the friction or clamping force." [Sheehan,

12/16/09 AM Tr. 38:1-8] He further agreed that in Figures 1 and 8, the friction force between the barrel and the retainer is greater than the spring force; and if it's not, the spring will just push the needle holder and the needle toward the back of the syringe. [*Id*. 39:21-40:3]

Because RTI and Mr. Sheehan's argument as to what "some" clamping or frictional force means is wrong as a matter of law, Mr. Sheehan's testimony that OMI's syringes infringe because there is an undefined amount of friction between the needle holder and barrel in the OMI syringes does not provide substantial evidence supporting the jury's verdict. That argument and evidence must be rejected as a matter of law.

RTI and Mr. Sheehan's other argument—that OMI's syringes infringe because the clamping or frictional force exceeds the spring force—is not supported by substantial evidence. The only evidence offered by RTI to demonstrate that the friction force exceeds the spring force in OMI syringes is Mr. Sheehan's conclusory opinion. *See, e.g., Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1080 (Fed. Cir. 2005) (no reasonable juror could find for the party based on speculative opinion). Mr. Sheehan admitted that he did not measure the friction force and the spring force to determine which is larger in the accused OMI syringes. He also admitted that he did not do any calculations of the spring force or the friction force. He further agreed that there is a lip on the inside barrel wall of OMI's syringes, but he did not measure the force required to push the needle holder past the lip toward the back of the syringe and he did not do any calculations of that force. [Sheehan, 12/16/09 AM Tr. 41:12-42:15] He testified, instead, that "there's a lot" of friction or clamping, but he did not say how much. [Sheehan, 12/15/09 PM Tr. 136:14-18] As Mr. Leinsing testified, however, one cannot determine whether the friction force is sufficient to keep the needle holder in place against the force of the spring simply by looking at OMI drawings as Mr. Sheehan did. "Any engineer knows that you have to do testing

to prove any observations. You need to do at least calculations, if not final testing to prove your hypotheses." [Leinsing, 12/17/09 PM Tr. 26:25-27:9] He further testified that testing must be done to determine the forces because of the presence of lubrication in the barrel (which he confirmed with OMI personnel) and the surface finishes between the component parts. [Leinsing, 12/17/09 PM Tr. 19:23-20:18 and 27:13-25]

Mr. Leinsing conducted extensive tests to support his opinions. He tested 30 samples of each size of OMI's syringe in the package, without altering the syringes in any way, which revealed that the spring simply pushed the needle holder back against the lip or flange. The friction force was not sufficient to hold the needle holder in place against the force of the spring. [DTX 1048; Leinsing, 12/17/09 PM Tr. 15:13-17:11] He also did further confirmatory tests in which he took a close-up of the flange or lip stopping the needle holder [DTX 1056; Leinsing, 12/17/09 PM Tr. 17:21-18:20], and he observed the spring pushing the needle holder out of the barrel when the lip was removed, demonstrating that the friction force in the barrel was insufficient to hold the needle holder in place against the force of the spring. [DTX 1051 and 1040; Leinsing, 12/17/09 PM Tr. 18:21-21:19] Mr. Leinsing also measured the friction, spring, and flange forces in one sample of each size of the OMI syringes. The data showed that the friction force in each case was less than the force of the spring, whereas the holding force of the flange was much greater than the spring force. [DTX 1126, 1050, 1062, and 1041; Leinsing, 12/17/09 PM Tr. 21:20-27:25]

Mr. Sheehan's only response to Mr. Leinsing's tests was to criticize them for altering the syringes. [*E.g.*, Sheehan, 12/15/09 PM Tr. 158:3-159:7] But, as Mr. Leinsing testified, his tests of 30 samples of each size of OMI's syringes in their packaging were conducted without making any modifications whatsoever to the syringes: "This was a really important test that I did,

because, basically, this test is taking an OMI syringe in the package; didn't open it, didn't alter it, didn't do anything." [Leinsing, 12/17/09 PM Tr. 15:24-16:2] Mr. Leinsing further testified that when he pushed down on the needle holder in his tests, the frictional force was actually increased as compared to any frictional force near the flange, because the syringe barrel has a slight taper in order to remove the core pin. [Leinsing, 12/17/09 PM Tr. 81:12-82:5]

RTI has the burden of proving infringement by a preponderance of the evidence. OMI does not have the burden of proving noninfringement. Mr. Sheehan's criticism of Mr. Leinsing's tests and his conclusory opinion that the friction force exceeds the spring force does not satisfy RTI's burden of proof. Accordingly, there is no literal infringement of the asserted claims as a matter of law because the OMI's syringes do not satisfy the "retainer" limitations.

Infringement under the doctrine of equivalents is also precluded as a matter of law based on the statements in the specification distinguishing the claimed syringes from the prior art Tsao '018 patent. "A patent applicant may limit the scope of any equivalence by statements in the specification that disclaim coverage of subject matter. (Citation omitted) Such limitations under the scope of equivalents are legal determinations…." *Frank's Casing Crew & Rental Tools, Inc. v. Weatherford Int'l, Inc.*, 389 F.3d 1370, 1376 (Fed. Cir. 2004). Here, the specification distinguishes the claimed invention's use of friction or clamping force between the retainer and barrel wall to hold the needle in the projecting position from the Tsao '018 patent's use of a flange on the barrel and friction for a fluid seal. Accordingly, there can be no infringement under the doctrine of equivalents as a matter of law because, like Tsao, OMI's syringes use a lip or flange on the barrel and friction for a fluid seal.

B. RTI Failed To Present Evidence From Which A Reasonable Jury Could Conclude That OMI's Syringes Satisfy The "Contact" Limitation Of The Claims

Claim 1 of the '584 patent recites "the tubular body having a head comprising a front tip configured to ***contact*** and separate the retainer member." Claims 18 and 24 recite a "front tip portion of the plunger" in their preambles and "the tip portion in ***contact*** with the transverse retainer member" in the "pushing" step. RTI did not assert that this limitation was met under the doctrine of equivalents. The only issue is literal infringement. The Court was not asked to construe the term "contact" during claim construction.

Here, the term "contact" should be given its ordinary meaning, i.e., touch. Mr. Sheehan admitted that the '584 patent claims require the plunger tip to contact the retainer and that the claims do not say that the plunger tip indirectly contacts the retainer. [Sheehan, 12/16/09 AM Tr. 43:18-25] Any argument that the contact limitation is satisfied by indirect contact is a doctrine of equivalents argument, not a literal infringement argument.

The evidence is undisputed that, in OMI's syringes, the seal covers the front tip of the plunger, and it is the seal, not the plunger tip, that contacts the outer portion of the needle holder (the structure that RTI asserts is the retainer). RTI stipulated that "the plunger seal pushes against the outer portion of the needle-holder causing it to move relative to the inner portion of the needle-holder." [12/16/09 AM Tr. 52:5-14] Mr. Sheehan admitted that the seal contacts the needle holder in OMI's syringes. [Sheehan, 12/16/09 AM Tr. 51:8-10] And Mr. Leinsing testified that OMI's syringes do not satisfy the "contact" requirement: "the front of the OMI plunger can't contact anything in front of it, because it has the plunger seal on top of it. It just simply can't touch it." [Leinsing, 12/17/09 PM Tr. 30:8-31:15]

Mr. Sheehan argued to the jury that the contact limitation is satisfied because the seal is part of the tip. [Sheehan, 12/16/09 AM Tr. 10:12-15] But that testimony is directly contradicted

by his report, where Mr. Sheehan stated that "the plunger has a plunger head, namely, the portion of the plunger where the plunger seal is located, including the plunger seal itself ***and*** a front tip portion." [Sheehan, 12/16/09 AM Tr. 50:21-51:1, emphasis added] On its face, this is an admission by Mr. Sheehan that the seal is not part of the tip; they are two separate components. Mr. Sheehan even admitted that in his report, he was describing the seal and the tip, and did not say that the seal is part of the tip.[1] [*Id.* at 51:2-7] This is consistent with Figure 17 in the '584 patent, which depicts the tubular body (recited in claim 1) as element 192 with a tip 200. The plunger seal, 196, is not part of that tubular body; it is mounted on the tubular body. [Leinsing, 12/17/09 PM Tr. 29:17-30:7] Referring to DTX 1117, Mr. Sheehan admitted that the white portion (the tubular body with the tip) in OMI's syringes never touches the needle holder. [Sheehan, 12/16/09 AM Tr. 51:8-52:4]

There is no substantial evidence in the record to support the jury's verdict that OMI's syringes satisfy the limitation in the claims that the tip of the plunger contacts the retainer. Judgment of non-infringement should be entered as a matter of law.

C. RTI Presented No Evidence Of Infringement Of The Unasserted Claims Of The '584 Patent

Judgment of non-infringement of the unasserted claims of the '584 patent should be entered as a matter of law. RTI only asserted claims 1, 2, 7, 18, 19, and 24 of the '584 patent. [Joint Stipulation of Partial Dismissal (Dkt. 206) at 1] RTI has not asserted claims 3-6, 8-17, 20-23, and 25-28 of the '584 patent and RTI presented no evidence of infringement of these unasserted claims. OMI has counterclaimed for a declaratory judgment of non-infringement, literally or under the doctrine of equivalents, of any valid and enforceable claims of '584 patent

[1] Mr. Sheehan's trial argument that the seal is part of the tip is also inconsistent with his opinion that the plunger tip does not contact the central part of the needle holder in the OMI syringe. The inconsistency arises because the central part of the seal does contact the central part of the needle holder, so the seal cannot be part of the tip. [12/16/09 AM Tr. 48:6-50:5]

[OMI's Third Amended Answer and Counterclaims (Dkt. 194) at 19] and has a right to judgment on these claims. Accordingly, judgment of non-infringement on the unasserted claims of the '584 patent should be entered as a matter of law.

Alternatively, OMI requests dismissal of the unasserted claims with prejudice. Prior to trial, the parties stipulated as to what issues were to be presented at trial and RTI dismissed with prejudice certain of its claims. [Joint Stipulation of Partial Dismissal (Dkt. 206) at 1] In this joint stipulation, RTI specifically stated that it was asserting claims 1, 2, 7, 18, 19, and 24 of the '594 patent [*id.*]; however, the accompanying order did not dismiss the remaining claims. [*See* Order on Joint Stipulation of Partial Dismissal (Dkt. 212)] Because the issues presented at trial were spelled out by the parties and the remaining contentions were dismissed with prejudice, the unasserted claims of the '584 patent should also be dismissed with prejudice.

IV. JUDGMENT THAT THE ASSERTED CLAIMS ARE INVALID SHOULD BE GRANTED AS A MATTER OF LAW

A. There Is No Substantial Evidence From Which A Reasonable Jury Could Conclude That The Claims Are Not Invalid For Lack Of Enablement

To satisfy the enablement requirement of 35 U.S.C. § 112, the specification of the '584 patent must teach those skilled in the art how to make and use the ***full scope*** of the claimed invention without undue experimentation. *Plant Genetic Systems N.V. v. Dekalb Genetics Corp.*, 315 F.3d 1335, 1339 (Fed. Cir. 2003). Where the specification enables one embodiment of the invention covered by the claims, but does not enable another embodiment, the claims are invalid for non-enablement. *See Automotive Technologies Int'l, Inc. v. BMW of North America, Inc.*, 501 F.3d 1274, 1281-82 (Fed. Cir. 2007) (affirming summary judgment of non-enablement because the full scope of the claims included mechanical and electronic side impact sensors, but electric sensors were not enabled); *Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371,

1378-80 (Fed. Cir. 2007) (affirming summary judgment of non-enablement because the full scope of the claimed inventions included injectors with and without a pressure jacket, and injectors without a pressure jacket were not enabled).

Factors to be considered in determining whether undue experimentation is required to make and use the invention include: "(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented in the specification, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims." *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

Here, the full scope of the claims includes (1) retainers and needle holders that are separate parts made of different materials; (2) retainers and needle holders made of different materials but joined together; and (3) retainers and needle holders that are formed in a single piece from one material.[2] Thus, the claims are broad under factor 8 of *Wands*. Also, it is undisputed that the level of skill in the art is relatively low (*Wands* factor 6). Mr. Sheehan defined the person of ordinary skill in the art as someone having less skill than you might expect for the medical device field. [Sheehan, 12/15/09 Tr. 118:23-122:9; Sheehan, 12/16/09 AM Tr. 56:7-14]

OMI presented evidence that the '584 patent fails to satisfy the enablement requirement for three separate reasons: (1) the specification does not enable welding together a retainer and needle holder made of different materials; (2) the specification does not enable forming the

[2] The third possibility must be included within the full scope of the claims, because in OMI's syringes, the needle holder and "retainer" asserted by RTI are molded in a single piece from one material. *See, e.g.*, *Plant Genetic Systems*, 315 F.3d at 1341 ("PGS concedes that the cell claims cover monocot cells. Only by doing so can PGS sue Dekalb, which makes monocot products, for infringement.")

needle holder and retainer in a single piece from one material; and (3) the specification does not enable the design of a separate retainer in view of the disclosure of Santoprene® 181-55 for the retainer. [Leinsing, 12/17/09 PM Tr. 49:7-54:15] In his rebuttal testimony, however, Mr. Sheehan only addressed the first non-enablement basis presented by OMI; he did not address the second or third bases. [Sheehan, 12/17/09 PM Tr. 146:14-149:9] Mr. Leinsing's second and third bases for non-enablement stand unrebutted.

With respect to forming the needle holder and retainer from a single piece of material, Mr. Sheehan admitted that the '584 patent does not describe how to mold the retainer and the needle holder from a single piece of material; it does not describe a single material that can serve the functions of both the retainer and the needle holder. [Sheehan, 12/16/09 AM Tr. 55:14-24] Thus, it is admitted that the '584 patent offers no guidance or direction as to making the needle holder and retainer from a single piece of material (*Wands* factor 2). Mr. Leinsing testified about the difficulty of molding the retainer and needle holder that are depicted in the patent from a single piece of material:

> It would be very difficult to come up with one material to meet all of the requirements of the '584 patent, because you have to meet the friction requirement; you have to meet the requirements of a tearing section in order to separate the needle-holder from the retainer; and then you have to have a rigid material in order to hold the needle.
>
> So even the current—the current design is using a softer material and a rigid material. So to have one material to meet all of those requirements would be very difficult if not impossible.

[Leinsing, 12/17/09 PM Tr. 52:4-18] He further testified that a person of ordinary skill in the art, after reading the patent specification, would not be able to mold the retainer and the needle-holder from a single piece without undue experimentation because "[y]ou would have to undergo quite a bit of experimentation to figure that out." [*Id.* 52:19-53:1] This is consistent with

Mr. Shaw's testimony that he spent years of trial and error experimentation to design a retainer for his syringe (*Wands* factor 1). This is clear and convincing evidence that the '584 patent does not enable the person of ordinary skill in the art to make and use the full scope of the claimed invention without undue experimentation. There is no substantial evidence supporting the jury's verdict that the claims are not invalid for lack of enablement.

OMI's third basis for non-enablement is also unrebutted. It is undisputed that the '584 patent discloses the use of Santoprene® 181-55 for the retainer. The specification does not disclose using Santoprene® 283-40 for the retainer, which is what RTI and Mr. Shaw actually used in the VanishPoint syringes. [Leinsing, 12/17/09 PM Tr. 38:22-39:5 and 45:10-13] Mr. Shaw admitted there was no data in the patent for a friction ring (retainer) made from Santoprene® 181-55. [Shaw, 12/15/09 AM Tr. 85:9-11]

Mr. Shaw also testified that the different hardnesses of Santoprene perform differently; that RTI tried to get away with one material for all three components, but they were not able to do so; that RTI tried "every which way" to use the same material, and they ended up with 40 Shore D for the plunger plug and retainer and 55 Shore A for the plunger seal; and that this was the optimal way to go, because the differences in performance were sufficient that they could not pick a universal hardness. [Shaw, 12/15/09 AM Tr. 88:9-91:16] He further testified that it took years to design the retainer and that he selected a configuration, size, and material for the friction ring by trial and error. [*Id.* 91:17-23]

Based on this evidence, Mr. Leinsing testified that undue experimentation would be required to design the retainer:

> It would take quite a bit of experimentation because somebody reading the patent would start out using 181-55. They would quickly discover that it doesn't work.

> And as we heard from Mr. Shaw, it takes a lot of–it took him a lot of testing to figure out the materials he used and hence it would take somebody ordinarily skilled in the art to do the same thing and it would take a lot of experimentation.

[Leinsing, 12/17/09 PM Tr. 53:16-54:9] He further testified that getting Santoprene® 181-55 to work for the retainer ring "would be very difficult, if not impossible. It's way too soft to satisfy all those requirements." [*Id.* 54:10-15] Mr. Sheehan did not rebut Mr. Leinsing's opinion.

There is no substantial evidence to support the jury's verdict that the claims are not invalid due to lack of enablement. Accordingly, judgment of non-enablement should be entered as a matter of law.

B. There Is No Substantial Evidence From Which A Reasonable Jury Could Conclude That The Claims Are Not Invalid For Failure To Disclose The Best Mode

Under 35 U.S.C. § 112, "the specification shall … set forth the best mode contemplated by the inventor of carrying out his invention." The Federal Circuit has set forth a two-step analysis to determine whether the best mode requirement has been satisfied. "First, the fact finder must determine whether, at the time of filing the application, the inventor possessed a best mode for practicing the invention." *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 963 (Fed. Cir. 2001). "Second, if the inventor possessed a best mode, the fact finder must determine whether the written description disclosed the best mode such that one reasonably skilled in the art could practice it." *Id.*; *see also, TALtech Ltd. v. Esquel Apparel, Inc.*, 2008 WL 2165996 at *3 (Fed. Cir. May 22, 2008); *Go Medical Indus. Pty., Ltd. v. Inmed Corp.*, 471 F.3d 1264, 1271 (Fed. Cir. 2006). The failure to disclose the best mode is not excused even if it is unintentional. *Consolidated Alum. Corp. v. Foseco Int'l Ltd.*, 910 F.2d 804, 808 (Fed. Cir. 1990).

OMI presented clear and convincing evidence that the best mode was not satisfied because all of Mr. Shaw's designs, as reflected in RTI drawings from May 1995 until years after

the '584 patent application was filed in August 2000, showed the retainer and plunger plug being made from Santoprene® 283-40, not Santoprene® 181-55, which was described in the patent as the best mode material for the retainer and plunger plug. [Shaw, 12/15/09 AM Tr. 81:25-84:20; Leinsing, 12/17/09 PM Tr. 40:2-42:16; DTX 107, 114-21] Mr. Shaw testified that he "tried every which way" to use the same material for the retainer, plunger plug, and plunger seal, and ended up with 40 Shore D for the plunger plug and retainer and 55 Shore A for the plunger seal; and that this was the ***optimal way to go***, because the differences in performance were sufficient that they could not pick a universal hardness. [Shaw, 12/15/09 AM Tr. 90:8-91:16]

RTI did not dispute any of the foregoing evidence. Instead, RTI created a new story for trial that Mr. Shaw did not testify about in his deposition. For the first time at trial, Mr. Shaw testified that his best mode was to make all three components (the retainer, plunger plug and plunger seal) out of the same material, even though in his deposition he testified that he tried "every which way" to do that and was not able to. At trial, he claimed that in 1994, he thought the best mode material for the retainer and plunger plug was Santoprene® 283-40, but that by the end of 1995, he had test data that demonstrated the feasibility of making all three components out of Santoprene® 181-55. [Shaw, 12/14/09 PM Tr. 154:17-157:19] Mr. Shaw's new story, however, is inconsistent with the other evidence.

First, although Mr. Shaw testified that he had supporting test data by the end of 1995 (Shaw, 12/15/09 AM Tr. 77:23-78:12], his assertion that Santoprene® 181-55 was the best mode material for the retainer and plunger plug was included in a patent application filed months earlier, on May 11, 1995. [*See* DTX 19, '733 patent, col. 12:58-13:3] The description of the best mode for the retainer and plunger plug material in the later-filed '584 patent is word-for-word identical to the one in the '733 patent. It was simply copied from the May 11, 1995 patent

application into the '584 patent at column 24, lines 12-25. [Shaw, 12/15/09 AM Tr. 79:1-81:7] Thus, Mr. Shaw's testimony that he thought 283-40 was the best material in 1994 but he put in his '584 patent that 181-55 was the best material in view of test results he had by the end of 1995 does not hold water, because he claimed in the '733 patent (filed in May 1995) that 181-55 was best, even though he did not yet have the test data he now claims.

Further, even though Mr. Shaw's new story at trial was that his best mode was to use the same material for the retainer, plunger plug, and plunger seal, he admitted that he did not tell the public in the paragraph at column 24, lines 12-25 of the '584 patent to use the same material for all three components. [Shaw, 12/15/09 AM Tr. 94:12-15] RTI tried to fix this unequivocal testimony in redirect by having Mr. Shaw testify that when he said that the plunger seal is "conventional" in column 24, lines 24-25, one of skill in the art would know that the material was 181-55. [Shaw, 12/15/09 PM Tr. 31:2-21] That testimony, however, is completely inconsistent with RTI's trade secret contentions in this case. RTI asserted that the particular hardness of the Santoprene® material for the plunger seal (which is 181-55) was an RTI trade secret. [Shaw, 12/15/09 AM Tr. 95:12-96:23] For the foregoing reasons, OMI has presented clear and convincing evidence that the best mode materials for the retainer, plunger plug, and plunger seal were not disclosed in the '584 patent.

OMI also presented clear and convincing evidence that Mr. Shaw's best mode of practicing the invention at the time he filed the '584 patent application included the use of a needle seat in the needle holder. Mr. Shaw testified that this feature had been incorporated into the design of RTI's VanishPoint syringes since 1997 and that a needle holder with a seat is better than a needle holder without a seat. [Shaw, 12/15/09 AM Tr. 98:8-99:8]; *Minco, Inc. v. Combustion Eng'g, Inc.*, 95 F.3d 1109, 1115-16 (Fed. Cir. 1996) ("The record must show that

the inventor considered an alternative mode superior to the disclosed mode.") Mr. Shaw also confirmed that this feature was not disclosed in the '584 patent. [Shaw, 12/15/09 AM Tr. 99:9-11] Mr. Shaw further testified that he was trying to maintain this feature as a trade secret. [*Id.* 99:12-100:6]

Mr. Leinsing testified that he reviewed drawings of the needle holder (DTX 146 and 147) from a time before the '584 patent application was filed until thereafter, and they depicted a seat in the needle holder. [Leinsing, 12/17/09 PM Tr. 47:18-25 and 48:7-17] He further confirmed that the '584 patent does not describe a seat in the needle holder. [*Id.* 48:20-22] Based on this, Mr. Leinsing testified that the '584 patent does not disclose Mr. Shaw's best mode for the needle holder. [*Id.* 49:2-6]

RTI did not contest these facts, but rather made two legally irrelevant arguments against OMI's best mode defense. First, RTI argued through Mr. Shaw and Mr. Sheehan that the use of a seat in the needle holder had nothing to do with the "invention," which, RTI claimed, involves tilting the retainer. [Shaw, 12/14/09 PM Tr. 163:16-22; Sheehan, 12/17/09 PM Tr. 150:11-22] That argument is wrong as a matter of law. The contours of the best mode requirement are defined by the scope of the ***claimed*** invention. *Northern Telecom Ltd. v. Samsung Electronics Co., Ltd.*, 215 F.3d 1281, 1286 (Fed. Cir. 2000). Although unclaimed subject matter is not subject to the disclosure requirements of § 112, *id.*, that is not the case here with respect to the needle holder. The needle holder is one of the elements recited in each of the asserted claims. Mr. Sheehan admitted this. [Sheehan, 12/17/09 PM Tr. 163:9-12]

Mr. Sheehan also suggested that Mr. Shaw did not need to disclose the use of a seat in the needle holder because "it's also a well-known way of holding a needle." [*Id.* 12/17/09 PM Tr. 150:11-19] It is true that to satisfy the best mode requirement, one need not disclose

production details that are "routine—i.e., details of production about which those with ordinary skill in the art would already know." *Great Northern Corp. v. Henry Molded Products, Inc.*, 94 F.3d 1569, 1572 (Fed. Cir. 1996). That argument, however, is completely inconsistent with RTI's position in this case that the way it used a seat in the needle holder was an RTI trade secret. RTI cannot, on the one hand, say that its use of a seat in the needle holder was a trade secret and then say that it was well known or routine. The best mode requirement does not permit patent applicants to keep as trade secrets best mode aspects of the claimed invention. *See* 3 Chisum on Patents § 7.05 [1][g] at 7-616 (2007) ("The best mode requirement forces the inventor to disclose information he might otherwise preserve as a trade secret.")

Accordingly, OMI has presented clear and convincing evidence that the '584 patent does not disclose the inventors' best mode for carrying out the claimed invention. There is no substantial evidence to support the jury's verdict to the contrary. Judgment should be entered that the claims are invalid as a matter of law because the inventors' best mode for practicing the claimed invention was not disclosed in the '584 patent.

V. JUDGMENT THAT OMI DID NOT MISAPPROPRIATE ANY RTI TRADE SECRETS SHOULD BE GRANTED AS A MATTER OF LAW

A. There Is No Substantial Evidence From Which A Reasonable Jury Could Conclude That RTI's Trade Secret Claim Is Not Barred By The Statute of Limitations

Texas law specifies that "a person must bring suit for misappropriation of trade secrets not later than three years after the misappropriation is discovered or by the exercise of reasonable diligence should have been discovered." Tex. Civ. Prac. & Rem. Code § 16.010(a). Also, under the statute, trade secret misappropriation that continues over time is a single cause of action. *Id.* at § 16.010(b). Thus, the first alleged misappropriation starts the statute of limitations clock ticking. The facts presented at trial show, by at least a preponderance of the evidence, that RTI's

misappropriation claim is barred because the first alleged act of misappropriation (OMI's alleged use of RTI's packaging materials) was known to RTI in March 2004, more than four years before this suit was brought.[3] The evidence also shows that RTI did not exercise reasonable diligence in investigating a possible claim for trade secret misappropriation.

RTI's man in China, Mr. Shao, testified that although he did not "know for sure" that OMI copied RTI's alleged packaging specification trade secrets, in March 2004, he took photographs of the packaging and then sent them to RTI back in Texas. [DTX 99B; PTX 1003; Shao, 12/15/09 PM Tr. 82:18-22, 83:22-85:6, 91:11-93:10] Mr. Shao further testified that the OMI packaging he saw was the same as RTI's; both were from a company called Fuzhou. [*Id.* 84:12-16] Mr. Shaw testified that although he "did not know for sure at that time that something was amiss," he was concerned that OMI was using RTI's alleged packaging trade secrets:

> Q. Now, when did you begin to suspect that there might be some problem?
>
> A. Well, eventually, through Steve Wisner, our Vice President, I heard that he—he had seen photographs, or whatever, of some packaging from the—one of the facilities over there that Double Dove owned. And concern had been raised to him, I guess, by Mike [Shao] that maybe Double Dove was not honoring their obligation to us to be our exclusive producer, exclusively producing for us.

[Shaw, 12/15/09 AM Tr. 36:5-17]

Despite this information, RTI waited until October 2004 before taking any further action. On October 5, 2004, RTI's lawyers (with Mr. Shaw's authorization) wrote a letter to OMI stating that Double Dove has "confidential and trade secret information of RTI" and that RTI was "prepared to take any legal action necessary to protect its patented and unpatented technology." [DTX 181; Shaw, 12/15/09 PM Tr. 5:19 - 7:1; Kiehne, 12/16/09 PM Tr. 159:21-160:20]

[3] RTI presented no evidence at trial that the statute of limitations should be tolled, for example, based on fraudulent concealment.

In response to RTI's letter, and at Mr. Kiehne's request, OMI's lawyer sent a letter to RTI's lawyers on October 15, 2004 requesting a copy of the contract between Double Dove and RTI, but OMI received no response to that letter. [DTX 857; Kiehne, 12/16/09 PM Tr. 160:21-161:17] Mr. Shaw could not even remember whether his lawyers showed him the letter from OMI's lawyer. [Shaw, 12/15/09 PM Tr. 8:13-9:12]

RTI then took no further action until almost 18 months later. On March 24, 2006, RTI's lawyers sent OMI another letter. The letter asserted that OMI had "misappropriated for its own purposes and benefited from the illegal and wrongful disclosure by Double Dove of confidential and proprietary technological and business information from RTI." [DTX 858; Shaw, 12/15/09 PM Tr. 9:14-10:15; Kiehne, 12/16/09 PM Tr. 162:6-163:5] There is no evidence that RTI did anything to investigate the possible misappropriation that it "suspected" between March 2004 (when the photographs were taken) and the March 2006 letter. RTI then waited another two years to file its trade secret misappropriation claim in this Court on April 1, 2008.

The knowledge and suspicions RTI had in March 2004 through Mr. Shao's photographs of OMI packaging in China were more than enough to satisfy the "discovered or by the exercise of reasonable diligence should have been discovered" standard of the Texas statute. That RTI had sufficient knowledge was confirmed in the accusations of trade secret misappropriation leveled against OMI in the October 2004 and March 2006 letters—particularly since there is no evidence in the record of any additional information RTI acquired between March 2004 and the dates of those letters.

The facts of this case are similar to those in *Seatrax, Inc. v. Sonbeck Int'l, Inc*., 200 F.3d 358 (5th Cir. 2000). In *Seatrax*, the Fifth Circuit affirmed summary judgment that Seatrax's trade secret misappropriation claim was barred under the new statute of limitations in Tex. Civ.

Prac. & Rem. Code § 16.010. Seatrax argued that it did not become aware of the alleged trade secret misappropriation until it filed suit, but the court held that events years earlier "should have put Seatrax on notice of possible misappropriation." *Id.* at 365. Even though Seatrax did not have confirmed evidence of misappropriation, the court noted that "suspicions should have abounded" and "the defendant's actions between 1991 and 1992 created a red flag for possible misappropriation of trade secrets." *Id.* at 366-67. The court concluded that "Seatrax failed to exercise reasonable diligence to discover its cause of action" and that Seatrax's claim for trade secret misappropriation accrued between 1991 and 1992 and was, therefore, barred by the Texas three-year statue of limitations. *Id.* at 367. Applying *Seatrax*, here, RTI's claim for trade secret misappropriation accrued by March 2004 when Mr. Shao took his photographs and sent them to RTI, and there is no evidence that RTI exercised reasonable diligence to further investigate this cause of action.

RTI tried to suggest to the jury that Mr. Shaw took prompt action to investigate after Mr. Shao took photographs of OMI packaging materials in China in March 2004. Mr. Shaw testified that he wrote Mr. Li requesting information on Mr. Li's involvement in OMI and permission to look at the plant, and that these requests were denied. [PTX 1011 and 903; Shaw, 12/15/09 AM Tr. 36:22-39:2] Cross-examination revealed, however, that Mr. Shaw did not did not make his request until November 9, 2006, over two and a half years after Mr. Shao took his photographs. [PTX 1011; Shaw, 12/15/09 PM Tr. 7:9-8:11]

RTI's counsel argued to the jury that RTI "didn't have to sue [OMI] until we were damaged, and that happened—as soon as that happened, we sued them. The damage completed the cause of action. That's when the accrual date was." [12/18/09 AM Tr. 136:12- 137:6] The argument that RTI suffered no "damage" until OMI commercially introduced its syringes was

disingenuous, because RTI has asserted that its damages include all unjust benefits that OMI purportedly enjoyed from the moment of alleged misappropriation, and including the alleged head start OMI enjoyed by using RTI's trade secrets back in 2003-04. For example, according to Prof. Hyman, Mr. Horstman's statement in 2004 that "I do not simply want to echo RTI's [packaging peel strength] spec" shows OMI used RTI's specification "as a guide to what you ought to do," i.e., as a head start. [PTX 320; Hyman, 12/16/09 AM Tr. 124:12-126:4] Regarding the packaging specification, Prof. Hyman also testified: "My focus was on the period I testified to and how they [OMI] acquired the knowledge and initially used it, not how they subsequently, if they did, moved on from there." [Hyman, 12/16/09 PM Tr. 19:13-16] Thus, in view of *Seatrax*, RTI's claim accrued by March 2004, and RTI's counsel simply misled the jury in arguing to the contrary.

RTI's argument was also wrong as a matter of law, because an action for trade secret misappropriation accrues under Texas law when a commercial use occurs, but commercial use is not limited to "commercialization" of a product as RTI argued to the jury. Rather, use includes use of a trade secret to improve an existing product or to accelerate the development and marketing of a new product, *see, e.g., General Universal Systems, Inc., v. HAL, Inc.*, 500 F.3d 444, 449-51 (5th Cir. 2007), which is precisely the kind of injury RTI has alleged in this case.

There is no substantial evidence to support the jury verdict that RTI's trade secret claim is not barred. Judgment should be entered against RTI on its trade secret misappropriation claim because it is barred as a matter of law by the Texas three-year statute of limitations.

B. RTI Did Not Present Substantial Evidence From Which A Reasonable Jury Could Conclude That OMI Misappropriated RTI Alleged Trade Secrets

At trial, RTI alleged that OMI misappropriated RTI trade secret test protocols and packaging specifications. RTI also alleged that OMI improperly acquired and used tests on RTI

packaging materials in support of its 510(k) submission. However, RTI failed to offer evidence to support a claim for misappropriation of these alleged trade secrets under Texas law. RTI had the burden to prove the following four elements to prevail on a misappropriation of trade secret claim in Texas:

(1) RTI owns a trade secret (as defined by Texas law);

(2) either OMI breached a confidential relationship with RTI to acquire the trade secret or otherwise improperly discovered RTI's trade secret;

(3) OMI used or disclosed RTI's trade secret; and

(4) RTI suffered damages proximately caused by OMI's conduct.

Trilogy Software, Inc. v. Callidus Software, Inc., 143 S.W.3d 452, 463 (Tex. App.—Austin 2004, pet. denied). RTI did not present substantial evidence to the jury on each of these elements.

1. RTI's Lost Profits And Unjust Enrichment Damages Evidence Is Irrelevant To Its Head Start Liability Evidence

At trial, RTI did not present evidence that OMI used any alleged RTI trade secrets in connection with the accused OMI syringes that have been imported into the U.S. since early 2008. RTI only presented evidence of alleged past use by OMI and asserted that this past use gave OMI a head start. That evidence, however, was irrelevant to RTI's damages evidence, which was based on use of alleged trade secrets in the accused OMI syringes, not head start. Therefore, there is no substantial evidence that any alleged damages suffered by RTI were proximately caused by OMI's conduct as required under Texas law.

Damages in trade secret misappropriation cases based on plaintiff's lost profits may be appropriate when the defendant actually used the trade secret in products or services that resulted in the plaintiff losing sales. *See, e.g., Jackson v. Fontaine's Clinics, Inc.*, 499 S.W.2d 87 (Tex. 1973) (defendant used patient data copied from plaintiff's files to solicit business, but submission

to the jury of a lost profits theory of damages reversed for failure to properly instruct the jury). Also, damages in a trade secret misappropriation case based on defendant's profits may be appropriate when the defendant actually used the trade secret in the product sold, resulting in profits to the defendant. *See, e.g., Elcor Chemical Corp. v. Agri-Sul, Inc.*, 494 S.W.2d 204, 210, 214 (Tex. App.—Dallas 1973) (plaintiff's lost profits and defendant's profits were proper bases for damages where defendant incorporated plaintiff's trade secrets in its product and process for manufacturing the product, but plaintiff failed to satisfy its burden of proving damages).

Here, however, RTI presented no evidence at trial that the accused OMI syringes commercialized beginning in early 2008 used either the alleged test protocol or packaging specification trade secrets. RTI's technical expert, Prof. Hyman, admitted that he did not review any OMI testing protocols or packaging specifications to compare them to the RTI testing protocols and packaging specifications that were being claimed as RTI trade secrets, and that he specifically did not present to the jury any documents from 2008-09 related to the accused OMI syringes. [Hyman, 12/16/09 PM Tr. 18:9-20:12 and 24:25-25:23] Instead, Prof. Hyman testified that OMI enjoyed a head start by using alleged RTI trade secrets back in 2003-04. For example, Prof. Hyman testified that Mr. Horstman's statement in 2004 that "I do not simply want to echo RTI's [packaging peel strength] spec" shows OMI using RTI's specification "as a guide to what you ought to do," i.e., as a head start. [PTX 320; Hyman, 12/16/09 AM Tr. 124:12-126:4] Regarding the packaging specification, Prof. Hyman also testified: "My focus was on the period I testified to and how they [OMI] acquired the knowledge and initially used it, not how they subsequently, if they did, moved on from there." [Hyman, 12/16/09 PM Tr. 19:13-16] [4]

Likewise, RTI's evidence regarding tests on VanishPoint packaging materials conducted

[4] Also, Mr. Kiehne testified that OMI has recently further changed its packaging specifications to conform to the specifications of a potential customer. [Kiehne, 12/16/09 PM Tr. 155:24-156:14]

by a Chinese university included by OMI in its 510(k) submission in April 2006 is not evidence of use in the accused OMI syringes in 2008-09. At best, it is head start evidence. This was confirmed by Mr. Bratic, who testified that OMI was "able to jump start that [510(k)] process" by submitting those packaging tests. [Bratic, 12/16/09 PM Tr. 91:5-25]

Thus, RTI's entire trade secret misappropriation case rests on RTI's contention that OMI gained a head start. This concession makes judgment as a matter of law mandatory, because RTI has a proof problem: RTI failed to introduce any evidence of head start damages. Instead, RTI contended that all of OMI's sales should be included in the damages calculations because OMI's former alleged use allowed OMI to enter the U.S. market. This is the wrong measure of damages. The proper measure of damages for this alleged former use would be head start damages. Mr. Bratic, however, offered no legally proper opinion on what the damages might be if OMI merely used RTI's alleged trade secrets in OMI's initial development of its products or to gain market entrance without also then using the alleged trade secrets in the accused OMI syringes sold in 2008-09. Mr. Bratic expressly did not perform a "head start" damage calculation, but rather did the same lost profits analysis that he did for patent damages. [Bratic, 12/16/09 PM Tr. 55:10-55:19] Mr. Bratic's testimony regarding lost profits and unjust enrichment was irrelevant to a "head start" misappropriation theory.

RTI has even conceded that Mr. Bratic did not opine on what the value of the trade secrets were at the time of the alleged misappropriation for purposes of head start damages. [*See* Plaintiff's Response in Opposition to Defendant's Motion for Partial Summary Judgment—Non-Patent Claims (Dkt. 165) ("RTI does not dispute that the report of Walter Bratic did not include specific dollar amounts or calculations of damages related to RTI's trade secret damages related to OMI's unjust enrichment through obtaining 'head start' in its manufacturing processes or

damages related to OMI's avoided costs")]. RTI has never offered evidence on how much (in terms of time) the supposed head start was or the value of the supposed head start that OMI allegedly enjoyed.

Thus, there was no substantial evidence of damages proximately caused by the head start that RTI alleges OMI obtained by using RTI trade secrets in the past. For this reason alone, judgment as a matter of law should be entered against RTI on the trade secret misappropriation claim.

2. There Was No Substantial Evidence That OMI Used Any Alleged RTI Testing Protocol Trade Secrets

RTI did not present substantial evidence showing that OMI ***ever*** used RTI's alleged test protocol trade secret information. At most, RTI demonstrated that OMI possessed alleged trade secret information. This failure is fatal to RTI's misappropriation case. *See Trilogy Software*, 143 S.W.3d at 463-65. In *Trilogy Software,* the plaintiff Trilogy Software ("TS") sued a former employee and a competitor, Callidus Software ("CS"), for trade secret misappropriation when CS hired TS's former employee, which allegedly used TS's trade secrets at CS. *Id.* at 455. The trial court granted the defendants' "no evidence" motion for summary judgment on all claims. *Id.* On appeal, TS claimed that there was a fact issue on whether defendants used TS's trade secrets at CS because both defendants had received an email from another TS employee that unquestionably contained TS trade secrets. *Id.* at 464-65. The court of appeals rejected this argument as a matter of law. The court held that Texas misappropriation law requires a showing that the defendant ***used*** trade secrets, not a showing that a defendant simply possessed trade secrets. *Id*. at 463-65. Evidence of possession is not evidence of use because it requires multiple inferences to reach the required showing of use, and "inferences stacked only upon inferences is no evidence." *Id.* at 465. The court concluded that defendants' mere receipt "does not raise a

genuine issue of material fact that [Defendants] actually used [TS's] trade secrets." *Id.*

The *Trilogy Software* case guts RTI's misappropriation claims related to the test protocols, because RTI failed to present evidence of actual use by OMI of the alleged test protocol trade secrets. Through Prof. Hyman, RTI at best cited documents authored by Tony Horstman suggesting access to RTI test protocol information, not use by OMI. [PTX 961, 531, and 586; Hyman, 12/16/09 AM Tr. 121:22-123:3; 12/16/09 PM Tr. 3:9-4:11 and 6:22-9:19] Prof. Hyman admitted that he never compared the RTI test protocols referenced in PTX 961 to OMI's test protocols. [Hyman 12/16/09 PM Tr. 24:25-25:23] Under *Trilogy Software,* evidence of possession is not good enough to satisfy RTI's burden of showing use.

Thus, RTI's assertions of trade secret misappropriation are merely conclusory and not evidence of use. *Duffy v. Leading Edge Products, Inc.,* 44 F.3d 308, 312 (5th Cir. 1995) ("conclusory allegations unsupported by concrete and particular facts will not prevent an award of summary judgment"). RTI had the burden to produce concrete and particular facts showing that OMI used the alleged test protocol trade secrets but failed to do so. This failure of evidence on the required use element for the alleged test protocol trade secrets is fatal. For this additional reason, judgment as a matter of law should be entered on RTI's trade secret misappropriation claim.

3. There Was No Substantial Evidence That Tests Conducted On RTI Packaging Materials By A University Were Trade Secrets Or Were Improperly Obtained By OMI

RTI argued to the jury that OMI misappropriated RTI trade secrets by including tests performed by a university on VanishPoint packaging materials in OMI's 510(k) submission. RTI did not present substantial evidence, however, to sustain its burden of proving that those tests were actually trade secrets or that they were improperly obtained by OMI.

The tests were not trade secrets because, as Mr. Shaw and Prof. Hyman both testified, the

packaging materials were submitted to the university for testing by a paper packaging company, and there was no confidential relationship between RTI and the packaging company. [Shaw, 12/15/09 AM Tr. 73:2-74:5; Hyman, 12/16/09 PM Tr. 33:1-34:17] And RTI presented no evidence that OMI improperly obtained the tests. The only evidence on this point was Mr. Kiehne's testimony that OMI ***properly*** acquired the packaging tests: "Well, anyone can get this test if you go to the paper—paper company that's listed there and actually pay for it and [they] own that test." He testified that this is how OMI obtained the tests. [Kiehne, 12/16/19 PM Tr. 174:11-175:2]. Further, Prof. Hyman admitted that OMI's inclusion of tests on predicate devices (here, packaging tests on the VanishPoint syringe) in its 510(k) submission is proper as long as the tests were properly acquired. [Hyman, 12/16/09 PM Tr. 34:18-35:4].

There was no substantial evidence that the packaging tests included in OMI's 510(k) were trade secret or improperly obtained by OMI. Accordingly, judgment as a matter of law should be entered on RTI's trade secret misappropriation claim for this additional reason.

VI. CONCLUSION

In view of the foregoing, OMI respectfully requests that the Court to set aside the jury verdict in its entirety and enter judgment that the claims of the '584 patent are not infringed, that the asserted claims of the '584 patent are invalid, and that OMI has not misappropriated any RTI trade secrets.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing was served upon all counsel of record who are deemed to have consented to electronic service via the Court's ECF system per Local Rule CV-5(a)(3) and via email on this 19th day of January , 2010.

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